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(71) Applicant and
(72) Inventor: **OLIVA, Roberto** [IT/IT]; N°2 Via Mar di Barents, I-41012 Carpi (IT).

(74) Agent: **NERI, Luciano**; Bugnion S.p.A., Via Emilia Est, no. 25, I-41100 Modena (IT).

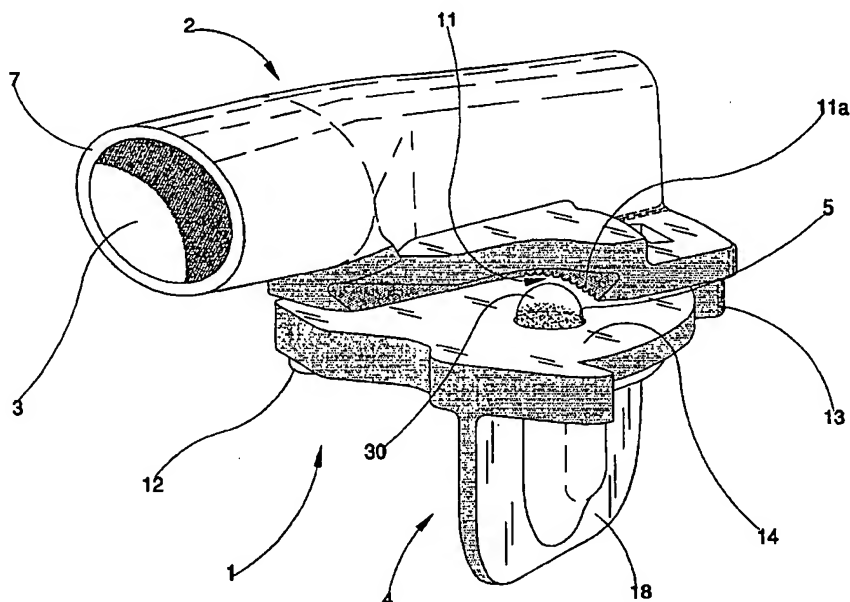
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(54) Title: **SINGLE DOSE INHALER**



(57) **Abstract:** The inhalator comprises a main body (2) affording an inhalation conduit (3); a second body (4) exhibiting a housing (5), into which a capsule (30) can be at least partially inserted; the second body (4) being rotatably coupled with the main body (2), and being able to rotate from an open position, in which the housing (5) is accessible from outside for insertion of a capsule (30), and a closed position, in which the housing (5) is in communication with the inhalation conduit (3); means for cutting (11) for cutting off a portion of a capsule (30) which projects from the housing (5) during rotation of the second body (4) from the open position to the closed position.

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Description

SINGLE DOSE INHALER

Technical Field

The invention relates to an inhalator for single-dose mixtures in capsules.

In particular, the inhalator enables inhalation of a mixture, typically powder, closed internally of a capsule made of plastic material which is wholly inserted into the inhalator.

5 Background Art

Inhalators of this type are known in the prior art and are constituted by a container comprising an inhalation conduit in communication with a chamber for housing a capsule containing a pharmaceutical substance to be inhaled. The housing chamber is elongate, and of a same shape as usual capsules for powder-
10 form drugs, and is transversally arranged with respect to a longitudinal development of the inhalation conduit. Means for breaking open the capsule are associated to the housing chamber and arranged at ends thereof; the means for breaking are constituted by two piercing devices, including a number of sharp teeth which penetrate the housing chamber. The teeth are kept in an external
15 position in relation to the chamber by a plurality of springs and exhibit a portion which is external to the container in which it is possible to exert a pressure with the fingers to cause perforation of the capsule. The powder can at this point exit from the capsule and be inhaled.

The known-type inhalators exhibit numerous drawbacks.

20 A main drawback is the presence of a relatively high number of components, considering the presence of the piercing devices, the springs and the manoeuvring

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ends of the piercing devices. Some of these components are in relative motion with respect to the container and there is therefore a liability of malfunctioning or jamming. These components also require careful assembly operations in order to function correctly, which lead to an increase in cost of the inhalator.

- 5 Prior art inhalators also exhibit some functional defects. Firstly, perforation of the capsule does not guarantee complete exit of the medicinal substance, as the openings created are at ends of the capsule and small in size. To favour exit of the substance the inhalator has to be shaken and several inhalations performed, and still without the certainty of having consumed all of the capsule's contents. The
- 10 position of the housing chamber, which is aligned with the inhalation conduit, is such that the passage of the medicinal substance from the chamber to the inhalation conduit is considerably obstructed. To favour inhalation the device has to be inclined in order to raise the inhalation chamber, and consequently the medicinal substance is not directly aspirated into the trachea but enters partly into
- 15 contact with the inside of the mouth and is thus less effectively absorbed by the patient.

The main aim of the present invention is to obviate the above-described drawbacks by providing an inhalator for single-dose mixtures in capsules, which is characterised by having a limited number of components.

- 20 A further aim of the present invention is to provide an inhalator in which the medicinal mixture is made available for inhalation by being completely transferred to the inhalation conduit.

A further aim of the present invention is to provide an inhalator in which the mixture is inhaled by means of a simple drawing-in of breath by the user.

25 **Disclosure of Invention**

Further characteristics and advantages of the present invention will better emerge from the detailed description that follows of an inhalator for single-dose mixtures

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in capsules, in a preferred but non-exclusive embodiment of the invention, illustrated purely by way of non-limiting example in the accompanying figures of the drawings, in which:

figure 1 is a perspective view of an embodiment of the inhalator of the invention,
5 in a first operating configuration;

figure 2 is a perspective view of the inhalator of figure 1 in a second operating configuration;

figure 3 is a perspective view of a first component of the inhalator of figure 1;

figure 4 is a perspective view of a second component of the inhalator of figure
10 1;

figure 5 is a view in section of the inhalator of figure 2.

With reference to the figures of the drawings, 1 denotes in its entirety the inhalator of the invention. It comprises a main body 2 having an inhalation conduit 3. The main body 2 comprises a first surface 10 which extends more-or-
15 less planarly and parallel to the longitudinal axis of the inhalation conduit 3 and exhibits a hole 8 for communication with the inhalation conduit 3. Advantageously the main body 2 can be made of a transparent material.

The inhalator 1 further comprises a second body 4 which exhibits a second surface 14 which is complementarily shaped with respect to the first surface 10
20 and is in contact there-with. A housing 5 is afforded in the second surface 14, in which a capsule 30 can be at least partially inserted. The second body 4 is rotatably coupled to the main body 2 so that it can rotate from an open position, in which the housing 5 is accessible from the outside for insertion of a capsule 30, to a closed position, in which the housing 5 is aligned with the hole 8.
25 Advantageously, the second body 4 can be made of a transparent material.

The inhalator 1 further comprises means for cutting 11 for cutting away, as will be better explained herein below, a portion of the capsule 30 which projects from

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the housing 5 during rotation of the second body 4 from the open position to the closed position.

The first surface 10 is, overall, shaped as a segment of a circle with an apex thereof located in an intermediate position with respect to the longitudinal development of the inhalation conduit 3. The first surface 10 comprises a pivot
5 12 which is perpendicular to the first surface 10 and is arranged in about the same position as the apex of the first surface 10; the first surface 10 exhibits a guide spur 13 which is perpendicular to the first surface 10 and has a lateral projection 13a and a strike surface 13b. The lateral projection 13a is an undercut afforded
10 on a lateral surface of the spur 13 so that the portion of pivot 12 which is close to the first surface 10 has a smaller section than the remaining portion of the pivot 12.

The means for cutting 11 comprise a cutting edge 11a, arranged peripherally on the first surface 10, which exhibits a sawtooth shape. As the first surface 10 and
15 the second surface 14 are in contact, during the rotation of the second body 4 from the open position to the closed position the portion of the capsule 30 projecting from the housing 5 interferes with the cutting edge 11a, and is cut by the sawtooth edge of the cutting edge. The cut portion remains external of the inhalator.

The inhalation conduit 3 exhibits a first opening 6 for aspiration of air from the outside, arranged on the first surface 10, and a second mouth 7 for inhalation of
20 a single-dose mixture. The hole 8 is arranged on the first surface 10 in an intermediate position between the first and the second mouths 6 and 7. The second mouth 7 is used by the user to aspirate the medicinal mixture, while air
25 passes through the first mouth 6 to enter the inhalator. To facilitate inlet of air through the first mouth 6, a channel can be afforded on the first surface 10, extending from the edge of the first surface 10 to the first mouth 6. In a correct

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use of the inhalator, once the capsule 30 has been cut, the inhalator is gripped in such a way that the housing 5 is vertical and the cut end of the capsule 30 is facing downwards. The medicinal mixture falls from the capsule 30 into the inhalation conduit through the hole 8 and into the flow of air which is taken in
5 through the first mouth 6 and entrained towards the second mouth 7 by the inhaling action exerted by the user.

The inhalation conduit 3 exhibits a longitudinal section which is similar to a venturi tube and the hole 8 is arranged at the smallest-section end, i.e. the gullet end. The medicinal mixture which drops down from the capsule 30 is very
10 effectively drawn into the air flow in transit towards the mouth of the user, and the depression which is created in the gullet section of the conduit 3 draws any residues of medicinal mixture left in the capsule 30 or the hole 8 into the conduit 3. To prevent blockage, the hole 8 internally comprises a baffle 9 arranged across a diameter of the hole 8.

15 The second body 4 comprises a seating 15 which faces onto the second surface 14 and is predisposed to be inserted on the pivot 12 and to achieve a rotatable coupling between the main body 2 and the second body 4, in which coupling the first surface 10 and the second surface 14 are in reciprocal contact, one sliding on the other. The seating 15 is afforded in the breadth of the second body 4 and
20 is oriented so that a lateral surface thereof is arranged perpendicular to the second surface 14. In the illustrated embodiment, the seating 15 exhibits a C-shaped transversal section and the pivot 12 has a cylindrical shape with a lateral flat area enabling the main body 2 and the second body 4 to be unhinged in a predetermined angular position.

25 The second body 4 further exhibits a ledge 16 made along an edge of the second body 4, a shape of which complements the undercut 13a of the guide spur 13 and which is predisposed to interact in contact with the undercut 13a. When the main

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body 2 and the second body 4 are coupled, the ledge 16 is inserted below the undercut 13a and rotations that tend to separate the first surface 10 and second surface 14 are prevented.

5 The second body 14 further comprises a strike surface 17, perpendicular to the longitudinal development of the ledge 16, arranged at an end of the ledge 16 itself, and predisposed to meet the strike surface 13b of the guide spur 13. The contact between the strike surface 17 and the strike surface 13b defines a limit to angular displacement between the first surface 10 and the second surface 14, which limit is the closed position.

10 To ease opening and closing of the inhalator, the second body 4 comprises a transversal manoeuvring surface 18, perpendicular to the second surface 14 and extending on the opposite side of the second body 4 with respect to the second surface 14. By acting on the manoeuvring surface 18 it is extremely simple to perform a cutting action on a capsule 30 inserted in the housing 5.

15 The inhalator of the invention offers important advantages.

First of all, it basically comprises only two components, assembly of which is extremely simple. The inhalator is thus decidedly economical to produce and is practically without risk of jamming or malfunctioning.

20 Secondly, the arrangement of the housing for the capsule, as well as the complete cutting-open thereof, make the contents of the capsule fully available for inhalation, giving the user the certainty of having completely inhaled the correct dose. If transparent materials have been used, the user can fully check, even more easily, that he or she has completed inhalation of the full dose.

25 Thirdly, as the medicinal mixture is deposited internally of the inhalation conduit and internally of the flow of air created by the user's aspiration, the inhalator can be kept in a horizontal position. In this horizontal position, the longitudinal axis of the inhalation conduit is aligned with the mouth of the user, which enables the

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medicinal powders to reach the trachea without depositing on the internal parts of the mouth.

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Claims.

- 1). An inhalator for single-dose mixtures in capsules comprising a main body (2) having an inhalation conduit (3), wherein:
the main body (2) comprises a first surface (10) which extends planar and parallel to a longitudinal axis of the inhalation conduit (3) and exhibits a hole (8) for
5 communication with the inhalation conduit (3);
the inhalator also comprises a second body (4) which exhibits a second surface (14), shaped complementarily to the first surface (10) and placed in contact with the first surface (10), on which first surface (10) a housing (5) is fashioned, into which housing (5) a capsule (30) can be at least partially inserted; the second
10 body (4) being rotatably coupled with the main body (2), and being able to rotate from an open position, in which the housing (5) is accessible from outside for insertion of a capsule (30), and a closed position, in which the housing (5) is aligned with the hole (8);
the inhalator also comprises means for cutting (11) for cutting off a portion of a
15 capsule (30) which projects from the housing (5) during rotation of the second body (4) from the open position to the closed position.
- 2). The inhalator of claim 1, wherein:
the first surface (10) exhibits an overall shape which is a segment of a circle, with an apex thereof located in an intermediate position with respect to a longitudinal
20 development of the inhalation conduit (3) and comprises a pivot (12) which is perpendicular to the first surface (10) and arranged at the apex of the first surface (10), and a guide spur (13) which is perpendicular to the first surface (10) and arranged along an arced edge of the first surface (10), the guide spur (13) having an undercut (13a) and a strike surface (13b).

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3). The inhalator of claim 2, wherein the means for cutting (11) comprise a cutting edge (11a), arranged peripherally on the first surface (10) and having a sawtooth profile.

4). The inhalator of claim 3, wherein the inhalation conduit (3) exhibits a first mouth (6) for aspiration of air from an outside environment, which first mouth (6) is arranged on the first surface (10), and a second mouth (7) for inhalation of a single-dose medicinal mixture, the hole (8) being arranged on the first surface (10) in an intermediate position between the first mouth (6) and the second mouth (7).

5). The inhalator of claim 4, wherein the inhalation conduit (3) exhibits a longitudinal section which is essentially a venturi tube, the hole (8) being arranged in a narrowed, gullet section thereof.

6). The inhalator of claim 5, wherein the hole (8) internally comprises a baffle (9) arranged across a diameter of the hole (8).

7). The inhalator of claim 6, wherein the second body (4) comprises:
a seating (15) which faces the second surface (14), which seating can be inserted on the pivot (12) to realize a rotatable coupling between the main body (2) and the second body (4) in which the first surface (10) and the second surface (14) are in reciprocal contact and slide one upon another;

a ledge (16), fashioned along an edge of the second body (4), which ledge (16) is complementarily shaped with respect to the undercut (13a) of the guide tooth (13) and which ledge (16) is predisposed to interact contactingly with the undercut (13a);

a ledge strike surface (17) which is perpendicular to a longitudinal development of the ledge (16) and which is arranged at an end of the ledge (16), the ledge strike surface (17) being destined to strike against the strike surface (13b) situated on the guide spur (13);

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a transversal manoeuvring surface (18), perpendicular to the second surface (14), which extends on an opposite side of the second body (4) with respect to the second surface (14).

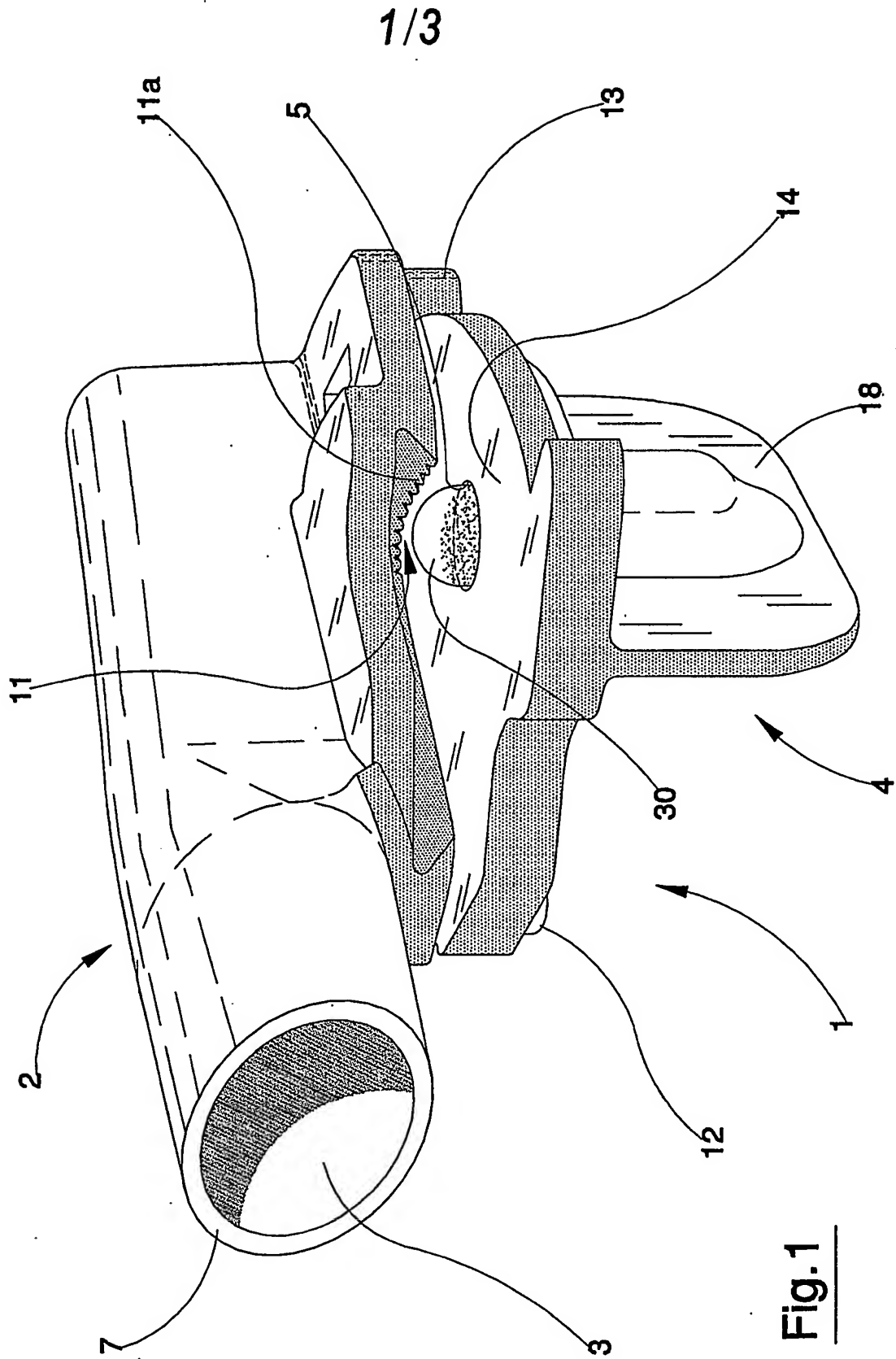
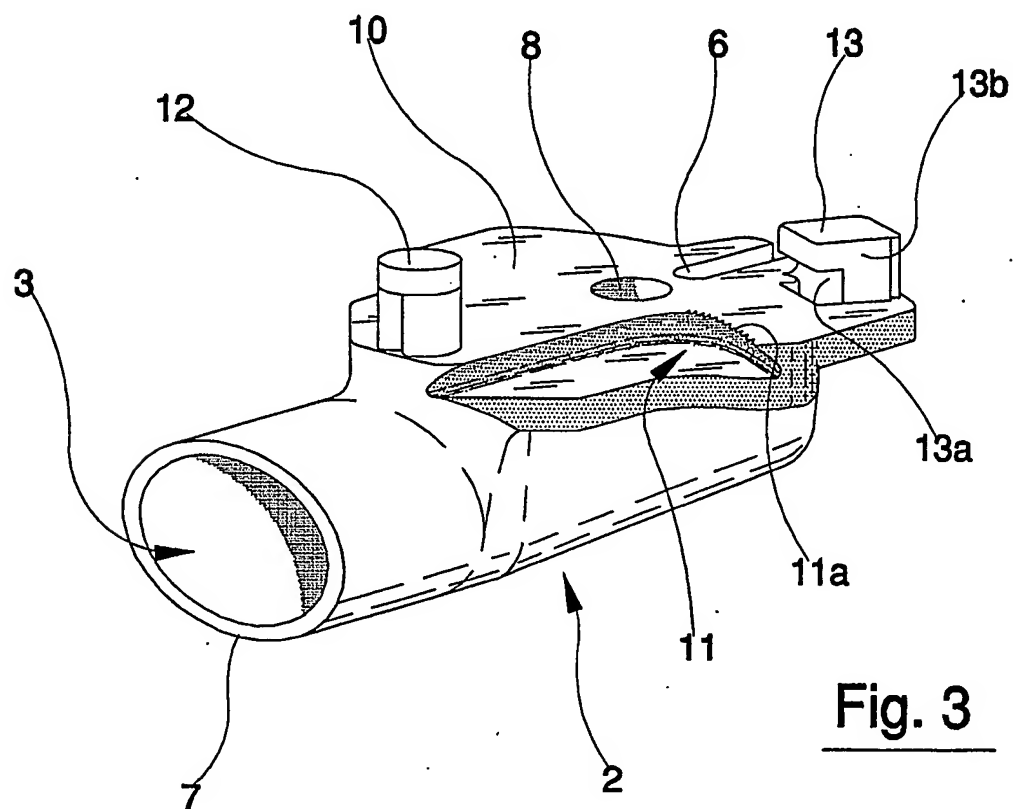
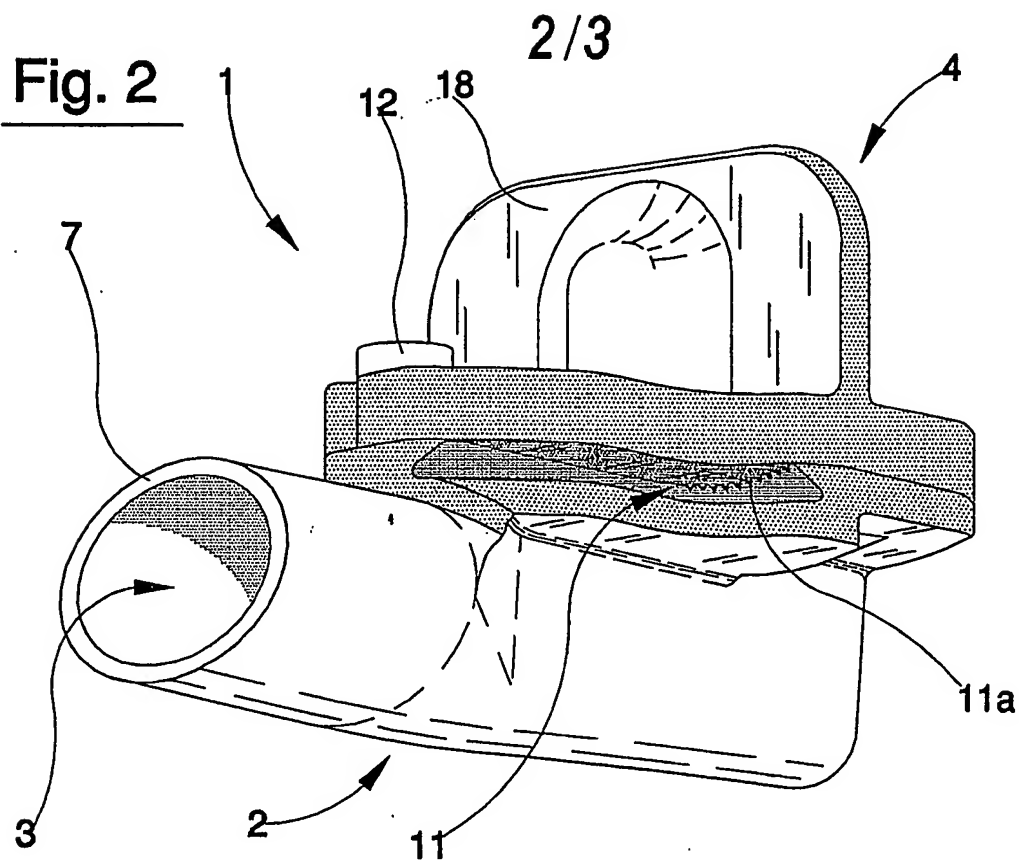


Fig. 1



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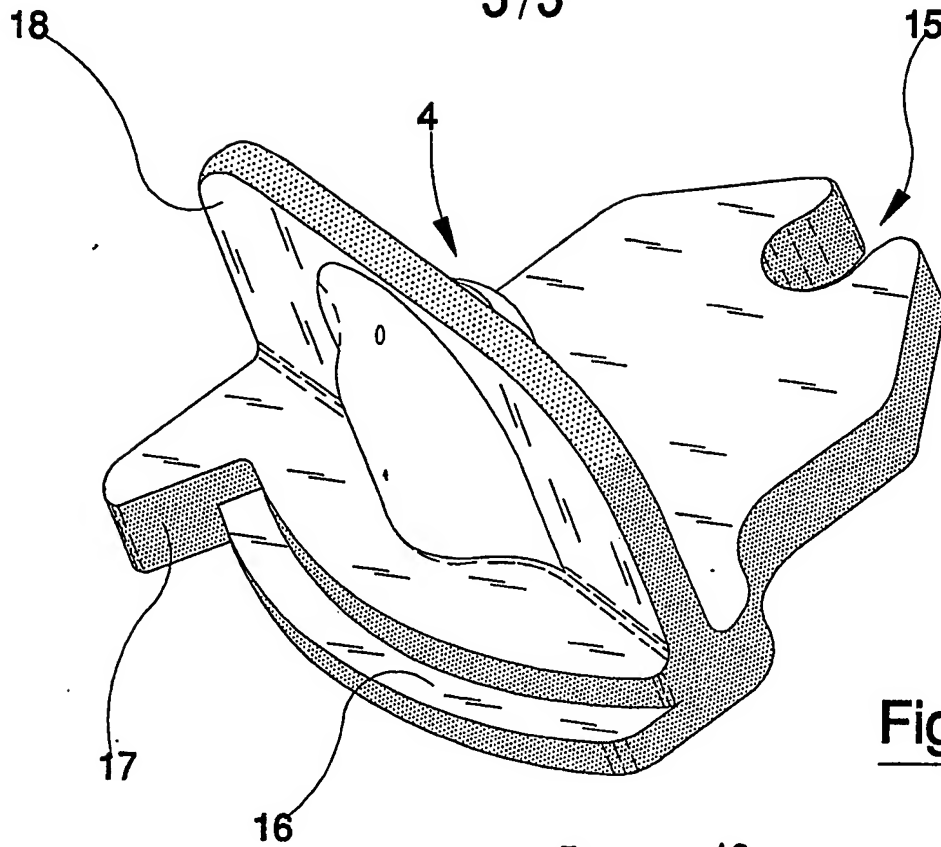


Fig. 4

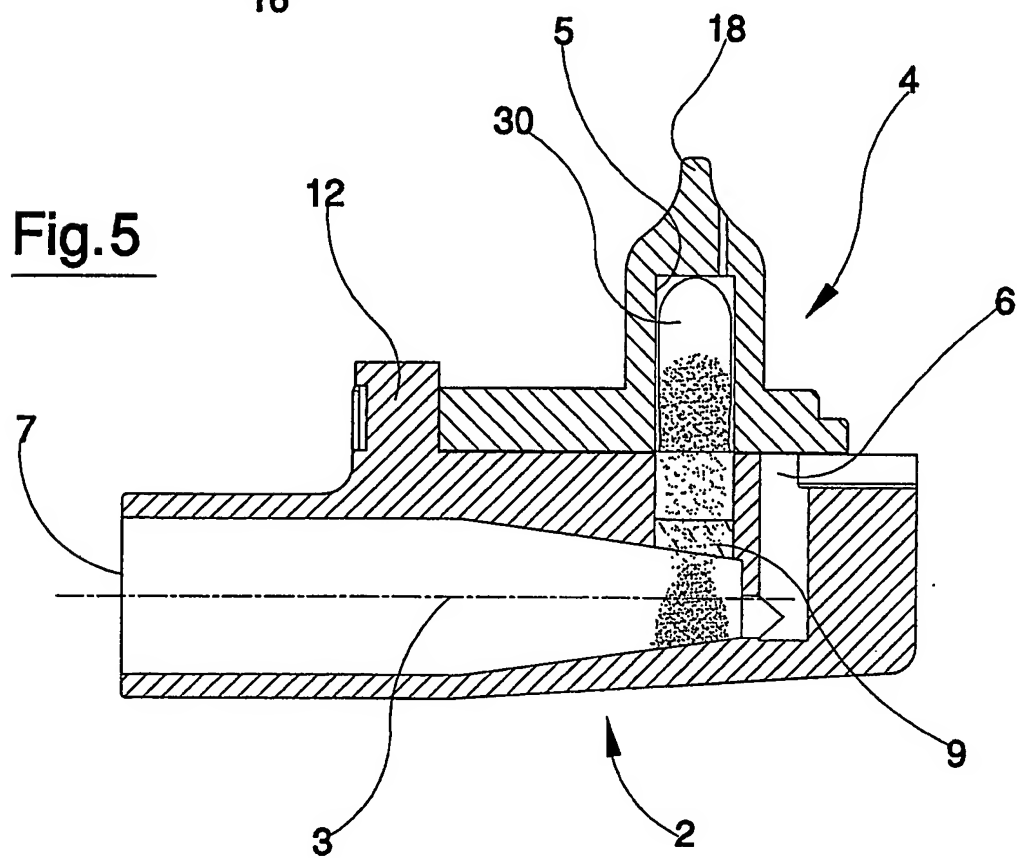


Fig. 5

INTERNATIONAL SEARCH REPORT

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A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61M15/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 1 238 680 A (PERA IVO) 11 September 2002 (2002-09-11) page 13, line 32 - line 47; figures 12,13,18-22 page 13, line 56 -page 14, line 31	1,2
A	WO 97 27892 A (HOERLIN ERNST) 7 August 1997 (1997-08-07) page 4, line 2 -page 11, line 22; figures 1-8	1
A	DE 196 37 125 A (SCHUCKMANN ALFRED VON) 19 March 1998 (1998-03-19) column 4, line 2 -column 6, line 17; figures	1
A	WO 01 87393 A (INHALE THERAPEUTIC SYST) 22 November 2001 (2001-11-22)	

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax (+31-70) 340-3016

Authorized officer

Zeinstra, H

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Information on patent family members

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Patent document cited in search report		Publication date	Patent family member(s)	Publication date
EP 1238680	A	11-09-2002	EP 1238680 A1	11-09-2002
			AT 255929 T	15-12-2003
			DE 60101451 D1	22-01-2004
			US 2002162552 A1	07-11-2002
WO 9727892	A	07-08-1997	AT 211401 T	15-01-2002
			AU 726740 B2	16-11-2000
			AU 1564197 A	22-08-1997
			BR 9707211 A	06-04-1999
			CA 2242181 A1	07-08-1997
			CN 1209755 A , B	03-03-1999
			CZ 9802189 A3	17-02-1999
			DE 69709851 D1	28-02-2002
			DE 69709851 T2	20-02-2003
			DK 877634 T3	25-03-2002
			EP 0877634 A1	18-11-1998
			ES 2170935 T3	16-08-2002
			HU 9901274 A2	28-03-2000
			IL 125171 A	29-05-2003
			JP 2000504248 T	11-04-2000
			NO 983341 A	24-09-1998
			NZ 326944 A	29-07-1999
			PL 328072 A1	04-01-1999
			PT 877634 T	28-06-2002
			RU 2179865 C2	27-02-2002
			WO 9727892 A1	07-08-1997
			SI 877634 T1	30-06-2002
			US 2001020472 A1	13-09-2001
DE 19637125	A	19-03-1998	DE 19637125 A1	19-03-1998
			AU 4382197 A	02-04-1998
			WO 9810817 A1	19-03-1998
WO 0187393	A	22-11-2001	AU 6167001 A	26-11-2001
			EP 1296732 A2	02-04-2003
			TW 491716 B	21-06-2002
			WO 0187393 A2	22-11-2001
			US 2002006316 A1	17-01-2002